REMARKS

STATUS OF THE CLAIMS

Claims 16-20 were pending. Claim 16 has been amended in the present amendment. Claims 17-20 have been canceled. Claims 1-15 and 21-23 were canceled previously as they were directed towards non-elected subject matter. New claims 24-30 have been presented. Claims 16 and 24-30 would be pending if the present amendment is entered.

Applicants request that the present amendments be entered as the amendments place the claims in condition for allowance or in better form for consideration on appeal.

I. REJECTION UNDER THE SECOND PARAGRAPH OF 35 U.S.C. § 112

The Examiner has rejected claim 16-20 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the wavy line associated with the chemical structure depicted in claim 16.

Applicants have amended claim 16 to delete the chemical structure associated with the wavy line, and have inserted the structure of formula I with a description of its substituents. Claims 17-20 have been canceled. Applicants respectfully submit that claim 16, and its dependent claims presently comply with the definiteness requirement of 35 U.S.C. § 112, first paragraph. Applicants respectfully request that this rejection be withdrawn.

II. REJECTION UNDER FIRST PARAGRAPH OF 35 U.S.C. § 112 – WRITTEN DESCRIPTION

The Examiner has rejected claims 16-20 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description of the genus of claimed compounds.

Applicants respectfully submit that the claims, as amended, are sufficiently described under 35 U.S.C. § 112, first paragraph. Claims 17-20 have been canceled. Applicants have amended claim 16 to delete the chemical structure associated with the wavy line, and have inserted the structure of formula I with a description of its substituents. The structural features recited in amended claim 16 provide sufficient details and relevant identifying characteristics to adequately convey to one of skill in the

art that the Applicants were in possession of the claimed invention at the time the application was filed. Accordingly, Applicants respectfully request that the written description rejection under 35 U.S.C. § 112 be withdrawn.

III. REJECTION UNDER FIRST PARAGRAPH OF 35 U.S.C. § 112

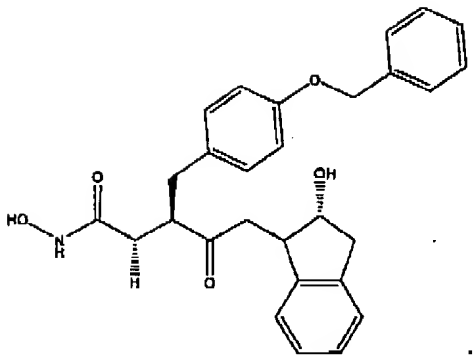
The Examiner has rejected claims 16-20 under 35 U.S.C. 112, first paragraph, as allegedly not being enabled for all carboxylic acid hydroxamide compounds with the desired aggrecanase activity.

Applicants respectfully submit that the claims, as amended, are sufficiently enabled under 35 USC § 112, first paragraph. Claims 17-20 have been canceled. Applicants have amended claim 16 to recite compounds of Formula I. On page 5 of the latest Office Action, the Examiner stated that the specification is enabling for compounds of Formula I. Accordingly, Applicants submit that the specification and the examples provided in the specification enable one of skill in the art to practice the claimed invention without undue experimentation. Accordingly, Applicants respectfully request that the enablement rejection under 35 U.S.C. § 112 be withdrawn.

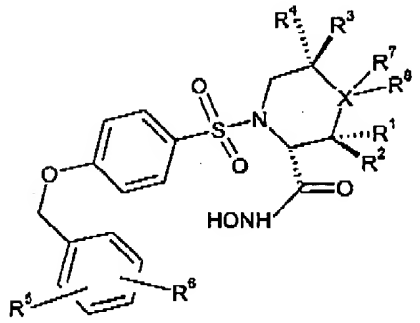
IV. REJECTIONS UNDER 35 U.S.C. §§ 102(e) and 103(a) - Yao '664

The Examiner has rejected claims 16-20 under 35 U.S.C. § 102(e) as allegedly being anticipated, or in the alternative, rendered obvious under 35 U.S.C. 103(a) by Yao ('664; U.S. Patent No. 6,576,664). The Examiner rejected claim 16 over the disclosure of a compound in Yao, compound 10, on col. 66, line 16.

Applicants respectfully submit that the claims, as amended, are not anticipated by Yao. Claims 17-20 have been canceled. Applicants have amended claim 16 to methods that relate to the use of a compound of formula I, or a pharmaceutically acceptable salt thereof. Compound 10 of Yao contains an indanyl moiety:



The compounds of formula I of claim 16, however, do not contain an indanyl moiety:



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Therefore, Yao does not anticipate claim 16.

Alternatively, the Examiner has stated that Yao renders claim 16 obvious under 35 U.S.C. § 103(a). However, there is no motivation or suggestion in Yao to modify a compound 10, which has an indanyl moiety, to arrive at a compound that lacks an indanyl moiety. Further, Yao does not provide a motivation or suggestion to link a hydroxamic acid group to a benzyloxyphenyl group through a N-sulfonyl-piperazine or a N-sulfonyl-piperidine ring. In addition, Yao does not disclose a compound with a hydroxamate directly bonded to a piperazine or piperidine ring. Therefore, Yao does not disclose all of the limitations of the claimed invention, such as a N-sulfonyl-piperazine or a N-sulfonyl-piperidine ring. Ergo, a prima facie case of obviousness has not been established. Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. §§ 102(e) and 103 be withdrawn.

V. REJECTIONS UNDER 35 U.S.C. §§ 102(e) and 103(a)- Duan '665

The Examiner has rejected claims 16-20 under 35 U.S.C. § 102(e) as allegedly being anticipated, or in the alternative, rendered obvious under 35 U.S.C. 103(a) by Duan ('665; U.S. Patent No. 6,376,665). The Examiner stated that 8 compounds in Table 1 of Duan anticipated claim 16, including a compound of Example 23 of Duan.

Applicants respectfully submit that the claims, as amended, are not anticipated by Duan. Claims 17-20 have been canceled. Applicants have amended claim 16 to methods that relate to the use of a compound of formula I, or a pharmaceutically acceptable salt thereof. Compound 23, and the other compounds of Table 1 that contain a benzyloxyphenyl group (e.g., compounds of Examples 18, 22, 31-32, and 45-50), have a hydroxamate moiety that is not directly bonded to a piperazine or piperidine group. Formula I of claim 16, however, has a hydroxamate group directly bonded to a piperazine or piperidine group. Accordingly, Duan fails to satisfy all of the limitations of claim 16. Therefore, Duan does not anticipate claim 16, under 35 U.S.C. § 102(e).

Alternatively, the Examiner has stated that Duan renders claim 16 obvious under 35 U.S.C. § 103. Applicants submit that Duan does not provide the requisite motivation or suggestion to modify a compound of Duan which does not have a hydroxamate directly bonded to a piperazine or piperidine ring to a compound of claim 16 which requires a hydroxamate group directed bonded to a piperazine or piperidine ring. In addition, Duan does not disclose a compound with a hydroxamate directly bonded to a piperazine or piperidine ring. Therefore, Duan does not disclose all of the limitations of claimed invention. It follows that Duan does not render obvious claim 16 of the present invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §§ 102(e) and 103 be withdrawn.

VI. REJECTION UNDER 35 U.S.C. § 102(e) - McClure '870

The Examiner has rejected claims 16-20 under 35 U.S.C. § 102(e) as allegedly being anticipated by McClure ('870; U.S. Patent No. 6,214,870). In particular, the Examiner stated that compounds of Examples 6-8, col. 35, l. 24 bridging to col. 37, line 30 each anticipated the claimed invention.

Applicants respectfully submit that the claims, as amended, are not anticipated by McClure '870. Applicants have amended claim 16 to methods that relate to the use of a compound of formula I, or a pharmaceutically acceptable salt thereof. Compounds 6-8 of McClure '870 contain a tetrahydro-cyclopenta[1,3]dioxole moiety coupled to a hydroxamate group. The compounds of formula I of claim 16, however, do not contain a tetrahydro-cyclopenta[1,3]dioxole moiety directly coupled to a hydroxamate. Instead, the compounds of claim 16 recite a hydroxamate group directly bonded to a piperazine or piperidine ring. Therefore, McClure '870 fails to disclose all of the limitations of claim 16. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 102(e) be withdrawn.

VII. REJECTION UNDER 35 U.S.C. § 102(e) - McClure '397

The Examiner has rejected claims 16-20 under 35 U.S.C. § 102(e) as allegedly being anticipated by McClure ('397; U.S. Patent No. 6,329,397). The Examiner stated that sixty-six compounds in McClure '397 fall with in the scope of claim 16, as they are hydroxamate compounds with a benzyloxyphenyl group.

Applicants respectfully submit that the claims, as amended, are not anticipated by McClure '397. Applicants have amended claim 16 to methods that relate to the use of a compound of formula I, or a pharmaceutically acceptable salt thereof. Claim 16, as amended, recites that at least one of R^1 and R^2 is methyl. Examples 1-3, 5, 9-33, and 36-79 of McClure '397, however, do not have at least one R^1 or R^2 methyl substituent. Claim 16, as amended, also recites that "when X is carbon and R^5 is para-halo, then at least one of R^6, R^3, and R^4 is not hydrogen." In Examples 4, 34, and 35 of McClure '397, X is carbon, and R^5 is a para-halo (fluoro), however all of R^6, R^3, and R^4 are hydrogen. Accordingly, McClure '397 fails to disclose a compound with all of the limitations of the claimed invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 102(e) be withdrawn.

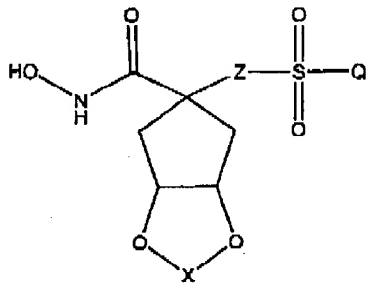
VIII. REJECTION FOR NON-STATUTORY DOUBLE PATENTING- McClure '870

The Examiner has rejected claims 16-20 for non-statutory obviousness-type double patenting over claim 30 of U.S. Patent No. 6,214,870. The Examiner has stated that claim 30 of McClure '870 is not patentably distinct over claim 16 of the present invention.

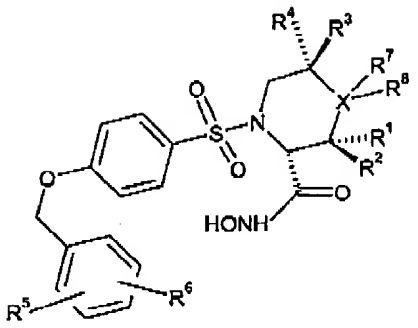
Applicants submit that claim 16 is not obvious for double patenting over claim 30 of McClure '870. Claim 30 of McClure recites:

> 30. A method for treating a condition selected from the group consisting of arthritis (including osteoarthritis and rheumatoid arthritis), inflammatory bowel disease, Crohn's disease, emphysema, acute respiratory distress syndrome, asthma, chronic obstructive pulmonary disease, Alzheimer's disease, organ transplant toxicity, cachexia, allergic reactions, allergic contact hypersensitivity, cancer, tissue ulceration, restenosis, periodontal disease, epidermolysis bullosa, osteoporosis, loosening of artificial joint implants, atherosclerosis (including atherosclerotic plaque rupture), aortic aneurysm (including abdominal aortic aneurysm and brain aortic aneurysm), congestive heart failure, myocardial infarction, stroke, cerebral ischemia, head trauma, spinal cord injury, neuro-degenerative disorders (acute and chronic), autoimmune disorders, Huntington's disease, Parkinson's disease, migraine, depression, peripheral neuropathy, pain, cerebral amyloid angiopathy, nootropic or cognition enhancement, amyotrophic lateral sclerosis, multiple sclerosis, ocular angiogenesis, corneal injury, macular degeneration, abnormal wound healing, burns, diabetes, tumor invasion, tumor growth, tumor metastasis, corneal scarring, scleritis, AIDS, sepsis and septic shock in a mammal, including a human, comprising administering to said mammal an amount of a compound of claim 1, effective in treating such a condition.

A compound of claim 1 of McClure '870 is a compound of formula I, where X is C=O or CR^3R^4:



Thus claim 30 relates to methods of treating the specified diseases with a tetrahydro-cyclopenta[1,3]dioxole or tetrahydro-cyclopenta[1,3]dioxol-2-one that is directly bonded to a hydroxamate group. Claim 16 of the present invention does not have a tetrahydro-cyclopenta[1,3]dioxole or tetrahydro-cyclopenta[1,3]dioxol-2-one:



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Instead, claim 16 recites compounds having a hydroxamate group directly bonded to a N-N-sulfonyl-piperazine or a N-sulfonyl-piperidine ring. Therefore, McClure '870 fails to disclose all of the limitations of claim 16. In addition, McClure '870 does not provide the requisite motivation or suggestion to modify the bicyclic dioxy tetrahydro-cyclopenta[1,3]dioxoles and tetrahydro-cyclopenta[1,3]dioxol-2-ones of claim 30 of McClure '870 to arrive at the monocyclic piperidine and piperazines of claim 16 of the present invention. Accordingly, Applicants respectfully request that the obviousness type double patenting rejection of claim 16 over McClure '870 be withdrawn.

IX. REJECTION FOR NON-STATUTORY DOUBLE PATENTING

The Examiner has rejected claims 16-20 for non-statutory obviousness-type double patenting over claim 68 of U.S. Patent No. 6,329,397. The Examiner has stated that claim 16 of the present invention is not patentably distinct over claim 68 of McClure '397.

Applicants have submitted herewith a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) to over come this rejection. Accordingly, Applicants respectfully request that the obviousness type double patenting rejection of claim 16 over McClure '397 be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at 734-622-7813.

Respectfully submitted,

Dated: 5/12/04

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